REMARKS/ARGUMENTS

The rejections presented in the Office Action dated January 16, 2008 (hereinafter Office Action) have been considered. Claims 1-62 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested. Claims 8-62 have been withdrawn by the Examiner.

Claims 1-2, 5, and 7 are rejected based on 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,003,975 to *Hafelfinger et al.* (hereinafter "*Hafelfinger*").

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (*Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). Therefore, all claim elements, and their limitations, must be found in the prior art reference to maintain a rejection based on 35 U.S.C. §102. The Applicant respectfully submits that *Hafelfinger* does not teach each and every element and limitation of independent claim 1, and therefore fails to anticipate at least this claim.

The Applicant's independent claim 1 recites, among other features, transitioning operation of the device from the monitoring mode, in which the energy delivery circuitry is disabled, to the energy delivery mode, in which the energy delivery circuitry is enabled, at least in part in response to coupling the cardiac lead to the lead interface.

Hafelfinger discloses an "implantable pacemaker having a unipolar/bipolar lead interchangeability." (Abstract; see also Col. 6, Lines 18-21). According to *Hefelfinger*:

> A unipolar lead is one in which stimulation occurs between the cathode tip and the pacemaker case, or anode. A bipolar lead is one in which stimulation occurs between the cathode tip, however, the anode is a ring electrode spaced approximately one inch from the cathode tip. (Col. 1, Lines 49-54; emphasis added).

As such, the device of *Hafelfinger* delivers stimulation in both the unipolar and bipolar configurations. *Hafelfinger* does not disclose that stimulation circuitry is disabled in either the unipolar or bipolar configurations. Rather, stimulation circuitry is used in both configurations to deliver cardiac therapy. (See, e.g., element 48B of Fig. 3). For at least this reason, the Applicant respectfully submits that *Hafelfinger* fails to teach a monitoring mode in which energy delivery circuitry is disabled, in the manner claimed.

*Hefelfinge*r further recites, as also reprinted on page 3 the Office Action, that:

> The present invention utilizes load recognition (i.e., the load impedance presented by the lead/tissue interface during a stimulation pulse) to determine the integrity of the implanted leads and to automatically change the electrode configuration to an available and operative configuration. That is, if the measured lead impedance does not fall within a prescribed range, the pacemaker will automatically change the electrode configuration between tip-to-ring and tip-to-case. (Col. 4, Lines 10-18; emphasis added).

The Applicant respectfully submits that the cited passage further underscores the differences between independent claim 1 and *Helelfinger*. For example, the device of *Helelfinger* changes between configurations when a lead impedance measurement taken during delivery of a stimulation pulse falls outside of a prescribed range to indicate a lack of integrity. (See above quoted passage; see also Col. 7, Lines 10-17). *Helelfinger's* device delivers a stimulation pulse to determine whether to change bi/unipolar configurations while claim 1 transitions from a mode with disabled energy delivery circuitry to a mode with the energy delivery circuitry enabled. As such, *Helelfinger's* change in configuration based on an impedance measurement taken during delivery of a stimulation pulse, which requires enabled stimulation circuitry, cannot correspond to the claimed transition to an energy delivery mode from a monitoring mode, in which the energy delivery circuitry is disabled in the monitoring mode.

The Office Action, in quoting Col. 4, Lines 30-41 of *Helelfinger*, states that:

> The device includes a "special monitoring circuit within the pacemaker that performs a lead impedance measurement whenever the operating configuration of the pacemaker is programmably changed, e.g., from bipolar to unipolar or vice versa. From this measurement, a determination is made as to whether the correct impedance is present for the existing operating configuration. If the expected impedance is not measured, then a different configuration measurement is made according to a predefined sequence until a correct impedance value is measured. The occurrence of a correct measurement is then used to set the pacemaker configuration accordingly." In other words, if a unipolar lead is sensed as connected to the device, the device is programmed to disable the energy delivery circuitry used in a bipolar lead. (Page 3).

The Applicant respectfully submits that the "in other words" recharacterization of *Helelfinger* is inaccurate. *Helelfinger* does not "disable the energy deliver circuitry used in a bipolar lead" when a unipolar lead is connected. *Helelfinger* does not disclose multiple sets of stimulation circuitries respectively associated with bipolar and unipolar configurations. (See element 40B of Figure 3). Rather, as discussed above, *Helelfinger* delivers stimulation using pacer stimulation stage 40B in both unipolar and bipolar configurations, and the configuration switch 80 to routes the stimulation pulse energy to the appropriate lead 12 or 14 depending on changes in operative configuration. (Col. 8, Lines 51-55). As such, the Applicant respectfully submits that *Helelfinger* does not teach disabling of energy delivery circuitry, in the manner claimed.

Moreover, the Applicant's independent claim 1 recites "a first electrode coupled to the housing and a second electrode" and then discusses the cardiac activity monitoring mode and the energy delivery mode associated with the combination of the first and second electrodes.

The Applicant respectfully submits that it does not appear that *Helelfinger* discloses a set of electrodes associated with both energy delivery circuitry and cardiac activity monitoring circuitry, wherein cardiac activity is sensed in a monitoring mode while the energy delivery circuitry is disabled. Even if *Helelfinger* switches sensing and stimulating using one electrode combination associated with a unipolar configuration to a different electrode combination associated with a bipolar configuration, *Helelfinger* does not disclose an electrode combination (e.g., first and second electrodes) associated with both cardiac activity monitoring (while energy delivery circuitry is disabled) and energy delivery (when the energy delivery circuitry is enabled) in separate modes. For example, when *Helelfinger* switches configurations (e.g., bipolar to unipolar), a different combination of electrodes must be used (e.g., from a tip-to-ring vector in a bipolar configuration to a tip-to-can vector in a unipolar configuration). Yet when modes are switched according to independent claim 1, the same electrodes (first and second) are used in both monitoring and energy delivery modes. As such, *Helelfinger* does not disclose a set of first and second electrodes associated with both an energy delivery mode and a cardiac activity monitoring mode with energy delivery circuitry disabled, wherein operation of the device is switched between modes at least in part in response to coupling a cardiac lead to a lead interface.

For each of the reasons discussed above, the Applicant respectfully submits that *Helelfinger* fails to teach each and every element and limitation of independent claim 1, and therefore cannot anticipate this claim.

Dependent claims 2, 5, and 7, which are dependent from independent claim 1, were also rejected under 35 U.S.C. §102(b) as being unpatentable over *Helelfinger*. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim, and recite additional features which further distinguish these claims from the cited reference. Therefore, dependent claims 2, 5, and 7 are also not anticipated by *Helelfinger*.

For at least these reasons, the Applicant respectfully submits that the rejection of claims 1, 2, 5, and 7 as being anticipated by *Helelfinger* is not sustainable, the withdrawal of which is respectfully requested.

Claims 3 and 6 are rejected based on 35 U.S.C. §103(a) as being obvious over *Hafelfinger* in view of U.S. Patent No. 5,318,593 to *Duggan* (hereinafter "*Duggan*"). Claim 4 is rejected based on 35 U.S.C. §103(a) as being obvious over *Hafelfinger* in view of U.S. Patent No. 6,205,357 to *Ideker et al.* (hereinafter "*Ideker*").

Each of claims 3, 4, and 6 depend from one of independent claim 1. Independent claim 1 is not obvious for at least the reason that the cited references do not appear to teach or suggest each and every limitation recited in each claim. Furthermore, while the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claim 1. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 3, 4, and 6 are not made obvious by *Hafelfinger,* even in combination with *Duggan* or *Ideker.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 3, 4, and 6 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, recharacterizations of cited references, common knowledge at the time of the Applicant's invention, officially noticed facts, and the like. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of

teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.048US01) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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